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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,357	03/30/2004	Seiichi Saito	A8739	4105

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EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	PAPER NUMBER
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,357	SAITO ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,18,20,21 and 34-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,18,20,21 and 34-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/22/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to the Amendment

The Amendment filed on 11/22/2006 in response to the previous Non-Final Office Action (7/26/2006) is acknowledged and has been entered.

Claims 16, 18, 20-21 and 34-37 are currently pending and under consideration.

Information Disclosure Statement

The Information Disclosure Statement filed on 11/22/2006 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(Note: The claim limitation "means for detecting binding between said antibody and RM2 antigen in a patient sample" is being treated under 35 U.S.C. 112, sixth paragraph.)

Claims 16, 18 and 20-21 **remain** rejected and **new** claims 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al. (J. Biol. Chem. 1994; 269: 5644-5652, IDS) in view of Cordon-Cardo et al. (US 5,168,043, 1992).

Saito et al. teach a monoclonal antibody referred to an RM2 (abstract). Specifically, the reference teaches (Title) that the RM2 antibody specifically recognizes the common tetrasaccharide epitope NeuAcα2→3Galβ1→3(NeuAcα2→6)GalNAc found in disialosyl galactosyl globoside's (DSGG's) which is present in the instant claimed RM2 antigen having the epitope structure:

GalNAcβ1→4**(NeuAcα2→3)Galβ1→3(NeuAcα2→6) GalNAc**β1→3Galβ1→R

(*emphasis added to show common "core" epitope*).

Saito et al. further teach a means for detecting the presence of DSGG by specific binding of the RM2 antibody to said DSGG, wherein the detection was carried out immunohistologically using RM2 antibodies and FITC-conjugated goat antibodies (page 5445, 2nd column, *Immunohistochemical Staining of Tissue Sections and Reactivities of tumor cell line with mAbs RM1 and RM2*). Moreover, Saito et al. teach that DSGG's are strongly expressed in urogenital epithelia of blood group A and B nonsecretor individuals, wherein nonsecretor females have shown a much higher incidence of repetitive urogenital *Escherichia coli* infection than secretor females (page 5651, 1st column, last paragraph). As such, Saito et al. teach that MAb RM2 is a useful reagent for evaluating the presence of these gangiolosides, DSGG's, in urogenital epithelia and predicting susceptibility to this type of infection (page 5651, 2nd column).

Saito et al. do not explicitly teach a kit comprising the RM2 antibody.

Cordon-Cardo et al. teach a diagnostic kit of use in determining whether an individual is a secretor which comprises a monoclonal antibody, which can be used for determining whether a female is susceptible to a urogenital infection comprising detecting the presence of an Le^a or Le^b antigen with a monoclonal antibody specific for said Le^a or Le^b antigen (column 3, line 65 to column 4, line 15 and column 4, lines 40-52). With regards to the kits, the patent teaches that the kits will

comprise monoclonal antibodies separately packed which will allow one to perform sequential testing (column 18, lines 43-49).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to package the antibody as taught by Saito et al. in the form of a kit for evaluating the presence of these gangiolosides, DSGG's, in urogenital epithelia and predicting susceptibility to this type of infection in view of Cordon-Cardo et al. teachings that kits comprising monoclonal antibodies allows one to perform sequential testing. One would have been motivated to do so because as taught by Saito et al. MAb RM2 is a useful reagent for evaluating the presence of these gangiolosides, DSGG's, in urogenital epithelia and predicting susceptibility to this type of infection. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by packaging the antibody as taught by Saito et al. in the form of a kit, one would achieve a kit which would allow one to perform sequential testing for the evaluating the susceptibility of an individual to an urogenital infection.

In response to this rejection, Applicants assert that Saito et al. (as well as the other cited references) do not teach the RM2 antigen recited in the present claims, and thus do not teach an antibody raised against the same. For example, Applicants assert that Saito et al. teach, in the abstract, raising antibodies against a different structure (DSGG, see page 5645, left column of Saito et al.). Moreover, Applicants assert that Saito et al do not teach raising antibodies against the recited antigen as isolated from a prostate cancer patient, as recited in new claim 37. As such, Applicants assert that the claims are therefore non-obvious over the cited references.

These arguments have been carefully considered, but are not found persuasive.

Regarding Applicants assertion that Saito et al. do not teach the RM2 antigen recited in the present claims, the Examiner acknowledges that Saito et al. does not explicitly teach the claimed antigen recited in the present claims. However, the Examiner recognizes that Saito et al. teach a monoclonal antibody referred to as RM2 antibody which recognizes the same epitope found in the claimed RM2 antigen. Moreover, the Examiner recognizes that the claimed antibodies raised against said RM2 antigen are directed to the epitope recognized by the RM2 monoclonal antibody taught in the prior art, see claim 21 of the present application. As such, the claimed antibodies appear to be the same as the prior art.

Note: New claims 34-37 have been included in the instant rejection because Saito et a. teach isolated antibodies which recognize common tetrasaccharide epitopes having the epitope structure: GalNAcβ1→4**(NeuAcα2→3)Galβ1→3(NeuAcα2→6) GalNAc**β1→3Galβ1→R (*emphasis added to show common "core" epitope*) presented by different carrier glycosylcermaides or O-linked peptides (page 5650, 1st column, 2nd line).

Therefore, NO claim is allowed

All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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